

readwell STRIP

ELISA Strip Analyser

USER MANUAL

Version – 3.4A



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TABLE OF CONTENTS

1. GENERAL INFORMATION	4
1.1. WARRANTY INFORMATION:	4
1.2. TECHNICAL SERVICE:	4
1.3. DISPOSAL INSTRUCTION:	4
1.4. CONTACTS:	4
2. GENERAL SAFETY WARNINGS	5
2.1. DANGER – WARNINGS SYMBOLS:	5
2.2. USE OF THE INSTRUMENT:	6
3. INTRODUCTION	7
3.1. DESCRIPTION:	7
3.2. SPECIAL FEATURES:	7
3.3. SPECIFICATIONS:	8
4. PACKING, TRANSPORT & STORAGE	9
4.1. GENERAL WARNINGS:	9
4.2. PACKING:	9
4.3. INSTRUMENT TRANSPORTATION:	9
4.4. STORAGE OF THE INSTRUMENT:	9
5. INSTRUMENT DESCRIPTION	10
5.1. PERSPECTIVE VIEW:	10
5.2. MICRO STRIP CARRIAGE:	11
5.3. INSTRUMENT WORKING PRINCIPLE:	12
6. INSTALLATION AND	13
6.1. UNPACKING INSTRUCTIONS:	13
6.2. PLACING THE INSTRUMENT:	13
6.3. POWER SUPPLY REQUIREMENTS:	13
6.4. PROTECTIVE GROUNDING:	13
6.5. THERMAL PRINTER:	13
6.6. START UP INSTRUCTIONS:	14
6.7. PRINTER SETTING OPERATIONS:	15
6.8. KEYBOARD CHECK:	15
6.9. SETTING DATE AND TIME:	15
6.10. TO ENTER CLINIC NAME:	16
6.11. CHECK LAMP AMPLITUDE:	16
6.12. STRIP LOADING PROCEDURE:	16
6.13. READINGS CHECK:	16
7. PRECAUTIONS	17

8. GENERAL KEY OPERATION	18
8.1. FUNC KEY:	18
8.1.1. Saving Test:	19
8.1.2. Deleting test:	19
8.1.3. Setting Date and Time:	20
8.2. MENU KEY:	20
8.2.1. Enter Clinic Name:	20
8.2.2. Recalling Saved Test:	20
8.2.3. Listing Saved Test:	21
8.3. LAMP KEY:	21
8.4. PAUSE KEY:	21
8.5. CLEAR KEY:	21
8.6. ENTER KEY:	21
8.7. INTRP KEY:	21
8.8. CTRL KEY:	22
9. GENERAL FUNCTIONS	24
9.1. SELECTING PRIMARY AND SECONDARY FILTERS:	24
9.2. BLANKING:	25
9.3. TO ENTER LOT NO. AND EXPIRY DATE:	25
10. PROGRAMMING MODE	26
10.1. ABSORBANCE:	26
10.3. A) CUT-OFF MODE:	28
10.3. B) REVERSE CUT-OFF MODE:	32
10.4. MULTI STANDARD MODE:	36
10.4.1. Linear Mode:	37
10.4.2. Point to Point Mode:	38
10.4.3. Plotting Graph:	39
10.5. PERCENTAGE ABSORBANCE MODE:	40
12. TROUBLE SHOOTING	42
13. DECONTAMINATION	43
13.1. DECONTAMINATION PROCEDURE:	43
13.2. PURPOSE OF DECONTAMINATION:	43
13.3. GENERAL CONSIDERATIONS:	43
13.4. PROCEDURE:	43
14. SAFETY CLEARANCE CERTIFICATE	44
15. SPARE PARTS	45
15.1. ORDERING SPARE PARTS:	45

1. GENERAL INFORMATION

1.1. Warranty Information:

Each Instrument is completely tested and guaranteed for twelve months from delivery. The warranty applies to all the mechanical and electrical parts. It is valid only for proper installation, use, and maintenance in compliance with the instructions given in this manual.

ROBONIK will at its discretion repair or replace parts, which may be found defective in the warranty period. The warranty does not include any responsibility for direct or indirect personal and / or material damages, caused by improper use or maintenance of the instrument.

Parts that are inherently subject to deterioration are excluded from the warranty. In case of defects due to misuse of the instrument, any incidental expenses like travel and man-hour service charges will be charged extra.

1.2. Technical Service:

ROBONIK is always accessible to the customers for any kind of information about installation, use, maintenance, etc. While asking for service, please refer to this manual, and report the printed serial number on the identification label.

Only qualified technicians are entitled to fix the instrument; the user, as described in this manual, should carry out ordinary maintenance.

ROBONIK's technical service or an authorized service center with specialized technicians, with suitable instrumentation and original spare parts are always available for extraordinary maintenance (repair), under a yearly maintenance contract or on specific demand.

1.3. Disposal instruction:

In case of removal or disposal of instrument, following instructions need to be followed

- Do not dispose in municipal waste; follow local regulations for instrument disposal.
- Plastic parts, Electronic PCBs and components can be recycled, so return back the instrument to manufacturer.

1.4. Contacts:

Manufacturer:

ROBONIK (INDIA) PVT LTD
A-374, TTC, MIDC Industrial Area,
MAHAPE, NAVI MUMBAI -400710
INDIA

Tel: +91-22-67829700,
Fax: +91-22-67829701

Email: sales@robonikindia.com
Website: www.robonik.in



2. GENERAL SAFETY WARNINGS

2.1. Danger – warnings symbols:

The following symbols are used to inform the user of the safety rules.



This symbol indicates generic danger. It means that, serious damage can occur to the operator if described precautions are not observed.



This symbol indicates HIGH ELECTRIC VOLTAGE. It is dangerous to touch any part having this label. Only qualified operators can access these components, after unplugging the instrument from the Supply.



This symbol indicates that the instrument involves the handling of samples, which can be infected (urine or human serum). In this condition, infection or contamination might occur. Pay attention to the general safety warnings when in presence of such biological substances. Use Protective clothes, gloves and glasses.



This symbol in the user manual indicates that damages to the instrument or erroneous results could occur if the given warnings are not followed.



This symbol indicates a portion, which is particularly important, and should be studied carefully.



This symbol indicates a Protective Earth or Ground terminal.

General Symbols



Symbol for “Manufacturer”



Symbol for “ IN VITRO DIAGNOSTIC MEDICAL DEVICE”

2.2. Use of the Instrument:

The instrument has to be used for the designed purposes under specified conditions, following proper procedures and safety rules, by qualified personnel.

THIS MANUAL CONTAINS INSTRUCTIONS FOR OPERATION BY QUALIFIED PERSONNEL ONLY.

- A qualified user has to make sure that the environmental condition is suitable, the installation is correct, the use and maintenance are proper, according to the general safety rules as well as to the particular precautions described in the manual (However, the user is not entitled to repair the instrument).
- A qualified technician is entitled to maintain and fix the instrument, according to the instructions given, using the original spare parts.
- Maintain room temperature and humidity as specified in the manual.
- The instrument has to be used as described in this manual. If it is not use the protection provided by the instrument may be impaired.
- ***Alterations to the instrument are strictly prohibited. The user is liable and solely responsible for any improper modification to the instrument, and for the consequences derived as a result.***
- Should the instrument need extraordinary maintenance, contact ROBONIK service or an authorized service center. Specialized technicians, who will be able to repair the instrument using original spare parts, will carry out the maintenance.
- This IVD equipment complies with the emission and immunity requirements as per IEC61326 series.



- **Warning :** This equipment has been designed and tested to CISPER11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference."

- An advisory that the electromagnetic environment should be evaluated prior to operation of the device.



- **Warning :** Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded international RF sources), as these may interfere with the proper operation.

3. INTRODUCTION

3.1. Description:

The readwell STRIP is a Micro Well Strip analyser. It is fully automatic with microprocessor control. It uses a built in ELISA algorithm to process and analyze data obtained from samples, and indicates interpreted results on the display screen or prints them on the thermal printer.

It is compact, light weight, portable, and it is designed to measure the samples either monochromatically or bichromatically, & interpret results accordingly.

The strip carriage is designed in such a way that the strip automatically moves and positions itself accurately in the optical measurement path. Readings are taken continuously, and the average value is calculated and results are presented according to the option selected. It is intended for in vitro diagnostic use.

3.2. Special Features

- Accommodates both 8 wells and 12 well strip configurations
- Accommodates both FLAT and ROUND BOTTOM wells.
- In-built Voltage Stabilizer ensures a wide voltage range thus not needing an external voltage stabilizer.
- A 20 column in-built Thermal printer for fast and silent printouts.
- Unique PAUSE options to note down the readings manually when printer is not available.
- Optional lamp saving mode.
- Selection of both primary and secondary filters.
- Blanking option.
- Date and time can be entered.
- Storing, deleting and recalling of tests.
- Multiple calibrator modes.
- Selection of duplicates for both calibrators and samples.
- Selection of Positive, Equivocal or Negative cut-off.
- Several pre-programmed calculation modes provide data processing of enzyme immunoassays. The following menu driven modes are provided for simple and error-free operations:
 - ✓ ABSORBANCE MODE
 - ✓ SINGLE CALIBRATOR MODE
 - ✓ CUT-OFF MODE
 - ✓ MULTI STANDARD MODE
 - ✓ % ABSORBANCE MODE
- Besides providing quick, accurate, reproducible results, the Instrument offers easy operation, versatility and economy. Each mode is described in detail later.

3.3. Specifications:

Linear measurement range	0.000 to 3.000 Absorbance Units (A)
Photometric Accuracy	$\pm 2 \%$ or 0.007 whichever is higher, from 0 to 1.5 A $\pm 3.0 \%$ from 1.5 A to 3.0 A
Drift	<0.007 A/hr
Photometric Linearity	2.2 A
Optical Measurement	Photodiode
Filters	
Type	Interference filter
Wave Length	405, 450, 492 and 630 nm
Half Bandwidth	10 nm $\pm$ 2 nm
Filter Selection	Automatic by stepper motor
Light Source	Tungsten Halogen, 6 V, 10 W
Warm – Up time	45 Seconds for 12 wells
Display	Four Line Back – lit LCD
Curve Plotting	Graphical representation on internal printer
Printer	Built in Thermal printer 20 columns 125 Open Channels
Analysis modes	Absorbance
	Cut – off
	Regression
	Single Standard
	% Absorbance
Power	
Wattage	50 Watts
Voltage	115 – 230 Volts $\pm$ 10 %, 50/60 Hz
Operating Conditions	
Temperature	From + 18 to 35 ⁰ C
Relative Humidity	Up to 85 %
Storage Condition	
Temperature	From – 10 to 60 ⁰ C
Relative humidity	Up to 85 %
Operating Position	On Horizontal flat, rigid and vibration free surface
Enclosure	ABS Fire Retardant
Size (cm)	32 x 35 x 11.5 (l x b x h)
Weight	5 Kg (Approx)

4. PACKING, TRANSPORT & STORAGE

4.1. General warnings:

Instrument has to be decontaminated before packing for transportation.

4.2. Packing:

Packaging is needed whenever it is to be transported or shipped by courier or other means.

To pack the instrument follow the instructions as below described:

- Decontaminate the instrument as explained in chapter No. 13 (Decontamination) of this manual.
- Place the instrument into the original packaging box; Instrument has to be properly protected by plastic protective material. Put copy of safety clearance certificate (copy of Safety Clearance certificate is attached at the end of this manual)
- Mark the package with address, instrument identification and warning labels.

4.3. Instrument transportation:

The transportation of the instrument in unpacked condition must be limited within the room where it is used, to avoid damage.

4.4. Storage of the instrument:

Before storing the instrument for a long period, pack it carefully as described above and store indoors.

Relative humidity has to be less than 85%, and temperature between 0°C and 50°C.

5. INSTRUMENT DESCRIPTION

This section describes different components of Readwell Strip from different views:

5.1. Perspective View:

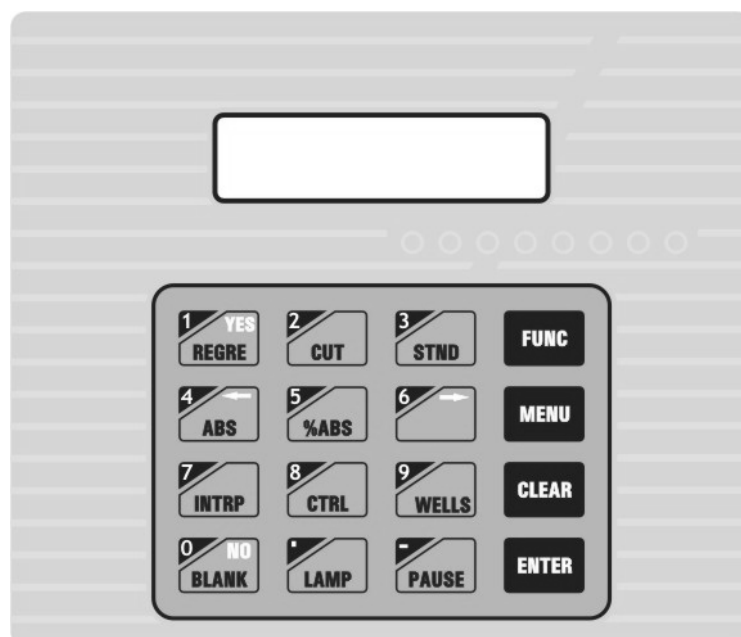


Components of different views of the below pictured instrument:

Front view:

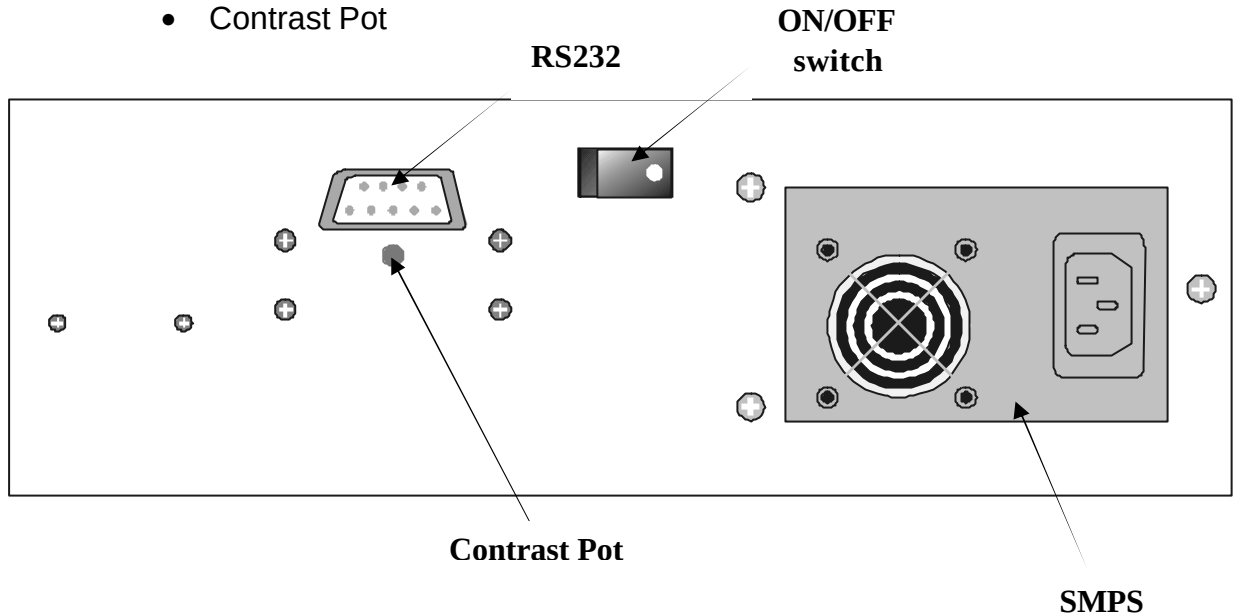
- Display.
- Alphanumerical key-pad.
- Micro-strip carriage
- Printer

The Keyboard has 16 Keys in 4X4 format



Rear View:

- Power socket and Mains switch,
- RS232 output connector
- Identification and QC passed label.
- Contrast Pot



5.2. Micro strip Carriage:

The instrument is provided with a carriage to convey the micro-strip towards the internal optical reader.

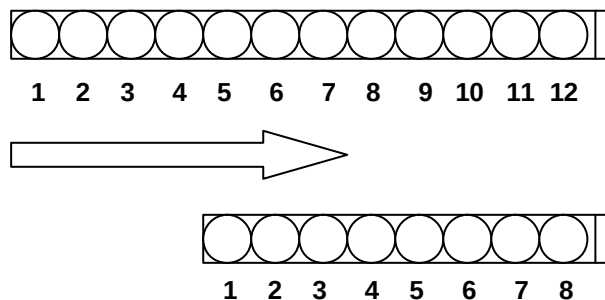
The micro-strip can have 8 or 12 wells. The program allows selection between these two possibilities:

Strip Carrier

- It supports both 8 well Strip and 12 well Strip
- It also supports less than 8 wells

Micro-strip positioning

The instrument has been programmed assuming that the micro-strip (8 or 12 wells) will be used in the order as indicated for each case:



Priority:

1. Blank (if requested)
2. Calibrators or Controls
3. Samples

Locate the micro-strip into the carriage; making sure that the micro-strip is properly inserted in the above-indicated order

Using Strip holder LOCK

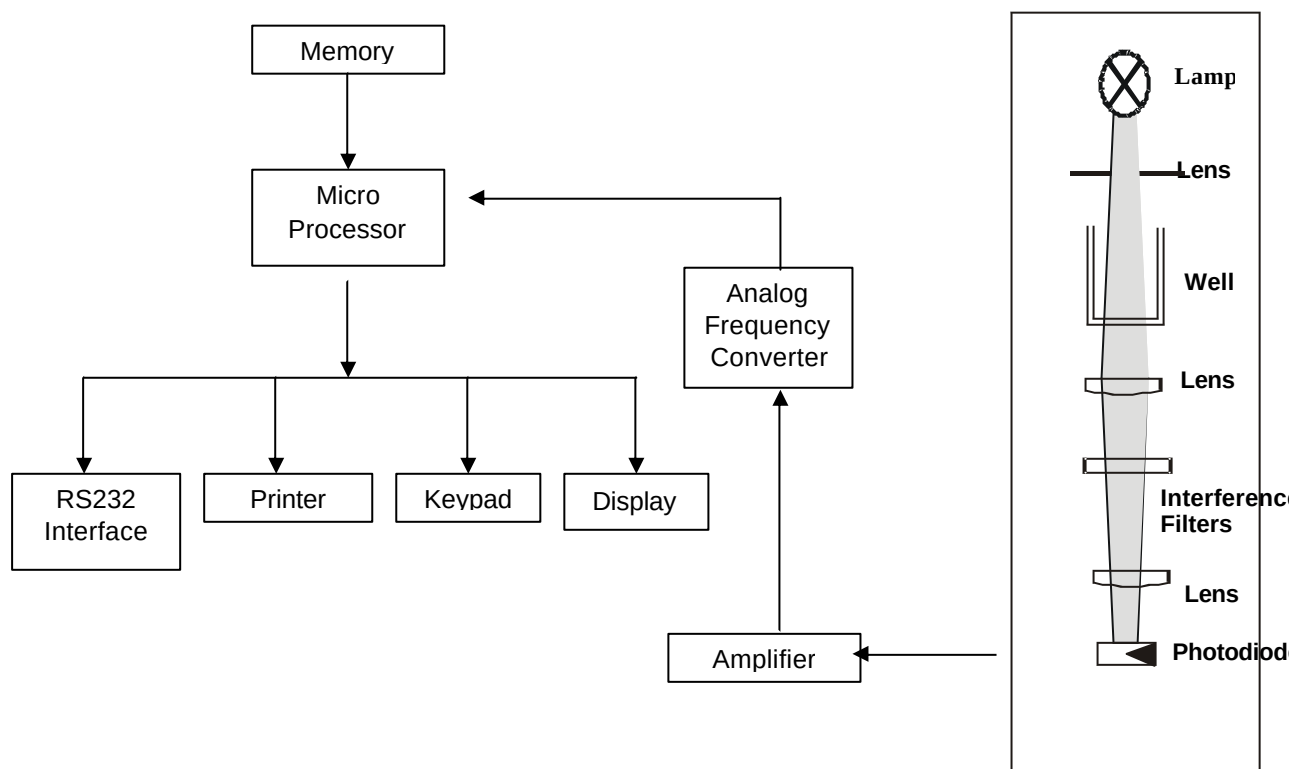
Place strip holder lock firmly to hold the strip in its position.

5.3. Instrument working principle:

On starting the test, the strip will be conveyed into the instrument.

Strip is moved in step by step by a well-controlled mechanism and each well is positioned precisely below the optical path. Optical density of each well is measured as explained below. Based on selected programming mode, sophisticated algorithms are used for analyzing the measured value & presenting the same on the printer, display & RS232 serial port for computer Interface.

White light produced by the lamp is focused into a beam by the lens & passes through the sample. Part of the light is absorbed by the sample & the remaining light is transmitted. It is filtered by interference filter & focused onto the photodiode. The photodiode converts the received light in to an electrical signal which is in-turn transformed into digital form, from which the microprocessor calculates the absorbance, taking in account of the blank & bio chromatic selection. The following diagram represents the main functional elements of the instrument:



6. INSTALLATION AND

VERIFICATION CRITERIA

6.1. Unpacking instructions:

Check accessories as per packing list.

Kindly store all packing materials so as to use it to repack and ship for maintenance or servicing.

6.2. Placing the instrument:

- The instrument has to be placed on a level bench.
- Room temperature should be between 10 and 35°C with a relative humidity below 85%.
- Protect it from direct sunshine

6.3. Power supply requirements:

Once the instrument has been placed, plug it into a power source by the locally available approved plug-in cable. Power cord should be CE, CSA, and UL marked. 115 - 230 Volts $\pm$ 10%, 50-60 Hz

6.4. Protective Grounding:

Warning: Please make sure that electrical power source is properly grounded.

6.5. Thermal printer:

The Strip analyser comes with built-in 20 columns Thermal Printer. User has to take proper care to handle this delicate instrument.

TIPS FOR CAREFUL USAGE OF PRINTER:

1. Do not pull the paper when loaded.
2. Lift the paper lever carefully and load the paper.
3. Keep the instrument clean and dust free.

Strip Analyser gives line feed automatically wherever it is necessary for clear reading like

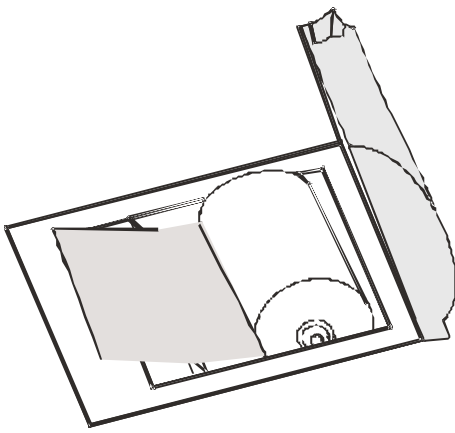
- a. While powering on.
- b. In between character lines, when display shows "load strip and press enter" by pressing **MENU** key line feed can be given

However user also can give additional line feed to move the paper forward by a character line.

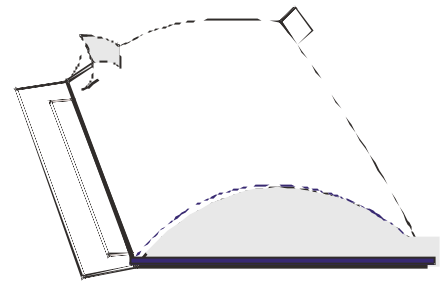
How to insert the paper

Insert the thermal paper roll by placing the sensitive side facing down. The sensitive paper side is recognizable by its smoother face.

Before inserting the paper



After inserting the paper



6.6. Start up Instructions:

- Switch on the instrument. The instrument will display the model name
- The instrument initializes all the parameters internally, and carries out a power on self-test. It then displays 'model name' and the time indicating that initialization is complete. If a printer is enabled, model name, the time and the date will be printed.
- If the correct date and time are not displayed, switch off the instrument and switch on again.
- Once initialization is over, a lamp located within the instrument will glow. This lamp requires 45 seconds for stabilization.

The instrument is now in IDLE mode, and ready for use.

6.7. Printer setting operations:

In case lever is disabled with printer in on condition/ or if printer has run out of thermal paper, following message will displayed

**“SET PRINTER PR ENTER”
“SKIP PRINTER PR YES”**

User may operate the instrument by disable the printer.

To Set Printer

- Press **FUNC** key
- Strip type Y/N
- Press **NO** key
- Delete test Y/N
- Press **NO** key
- Set time Y/N
- Press **NO** key
- Set printer Y/N
- Press **NO** key to switch off the printer, press **YES** key to switch On the printer

6.8. Keyboard check:

Check key board by pressing MENU key first and all other keys later, one should get a beep and either alpha numerical or numerical should appear on display

6.9. Setting Date and Time:

- Setting of date and time can be done with the help of FUNC key
- Press **FUNC** key
- Strip type Y/N
- Press **NO** key
- Delete test Y/N
- Press **NO** key
- Set time Y/N
- Press **YES** key
- The instrument displays DATE DD.MM.YY
- Enter date month and year in the same format
- Press **ENTER** key
- The instrument displays TIME HH.MM.SS
- Enter hour, minutes and seconds in 24 hr format.
- Press **ENTER** key
- The instrument goes back to idle position

6.10. To Enter Clinic Name:

- Press **MENU** Key
- Choose Test
- Enter **132** press **ENTER** Key
- Clinic Name Y/N
- Press **YES** key
- ABCDEFGHIJKLMN
- Select the characters using arrow keys, key No. **4** and **6**, confirm by pressing **ENTER** on blinking character. Conclude by pressing **ENTER** key twice at the last character, a maximum number of 15 characters can be entered.

6.11. Check lamp amplitude:

- Press **MENU** key
- Press **128** and press **ENTER** key.
- The instrument will print lamp amplitude in the following format

405 Amplitude **450** Amplitude
492 Amplitude **630** Amplitude

The amplitude should be in the range of 3.00 to 11.00

After printing amplitude press **FUNC** key once the instrument shall display SAVE TEST Y/N. press **CLEAR** key twice to go back to idle position.

6.12. Strip loading procedure:

Refer 5.2 Micro strip Carriage

6.13. Readings check:

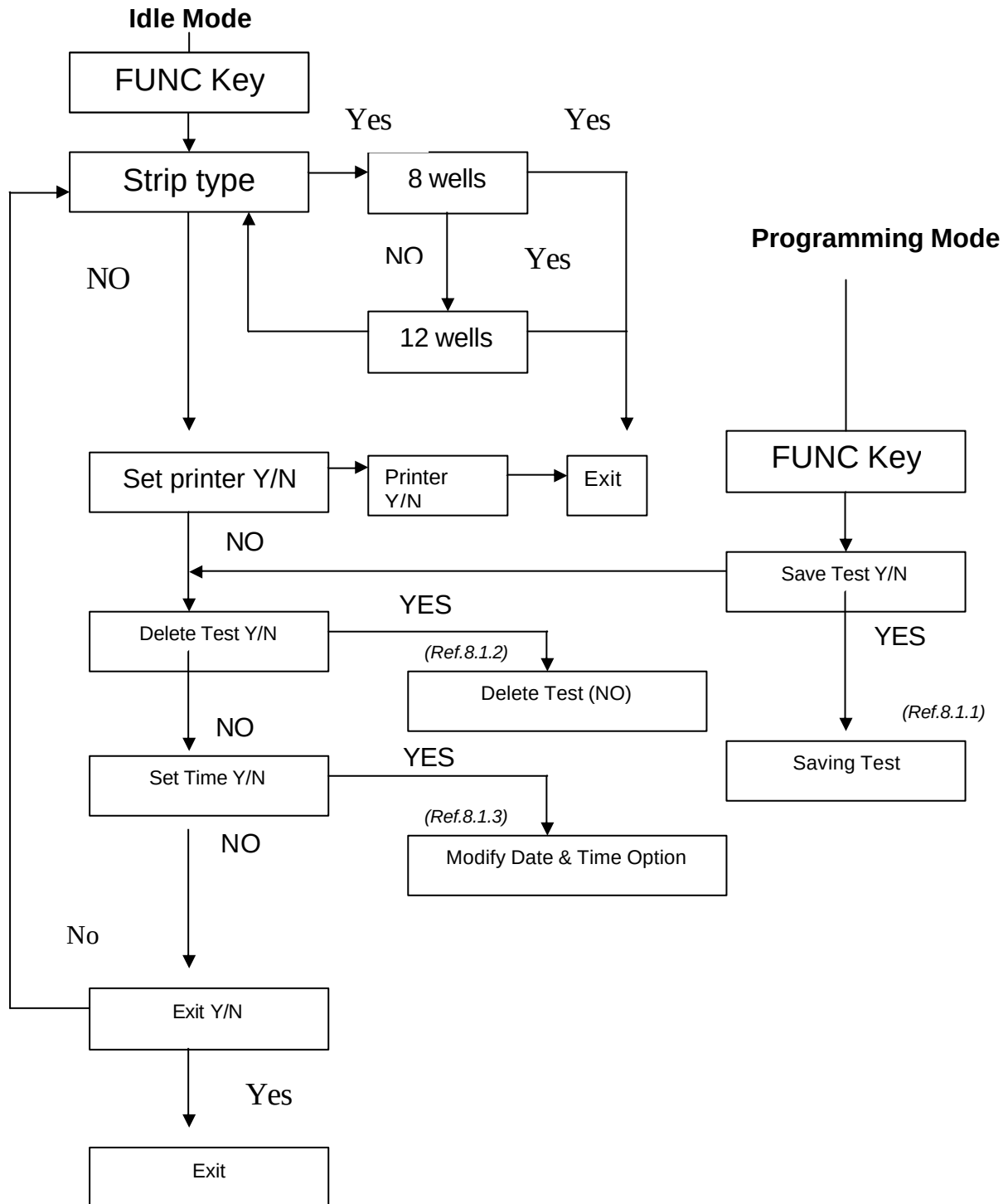
Checking of readings has to be done through controls and should be with range specified in data sheet of controls (care should be taken while preparing and pipetting controls and reagents, reagent and control expiry dates need to be checked.)

7. PRECAUTIONS

- ◆ Ensure that the main power switch is in OFF position before connecting the power cord.
- ◆ Confirm proper grounding for trouble free operation.
- ◆ Never operate the instrument with ground wire removed.
- ◆ After placing the strip, place the strip holder lock firmly
- ◆ Do not attempt to open the instrument or make repair without proper technical training.
- ◆ Do not allow unauthorized persons to operate or repair the instrument.
- ◆ Use a clean strip, and follow the instructions for blanking and standardizing.
- ◆ Do not read any wells containing bubbles.
- ◆ The volumes of sample, calibrators and blanks should be identical for correct readings, since the absorbance is proportional to the path length.
- ◆ Pipetting should be proper.
- ◆ Monitoring of the printed or displayed values during operation may help detect an error in making.
- ◆ Check the linearity and calibration of the instrument regularly against some standard reference.
- ◆ Check the micro-wells before use. They should be scratch free.
- ◆ Recheck the readings of high OD (above 2A).
- ◆ Dilute the sample and take another reading to confirm.
- ◆ Place strip holder locks firmly in the strip holder to ensure the strips are in its place to prevent error while reading optical densities of the samples.

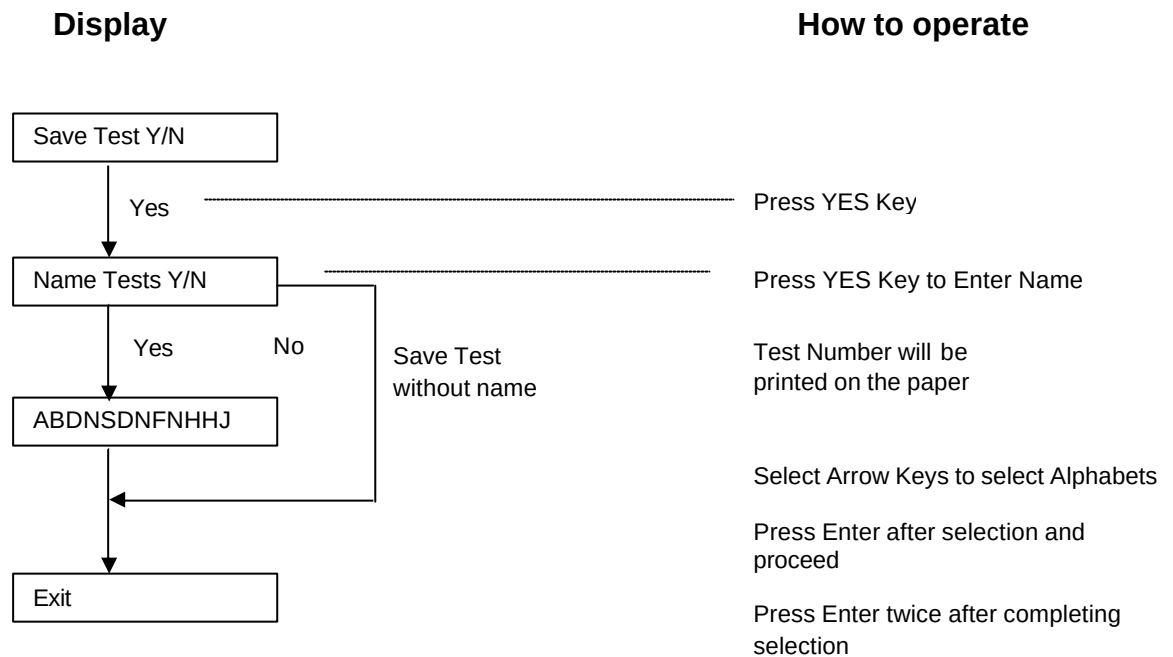
8. GENERAL KEY OPERATION

8.1. FUNC KEY:

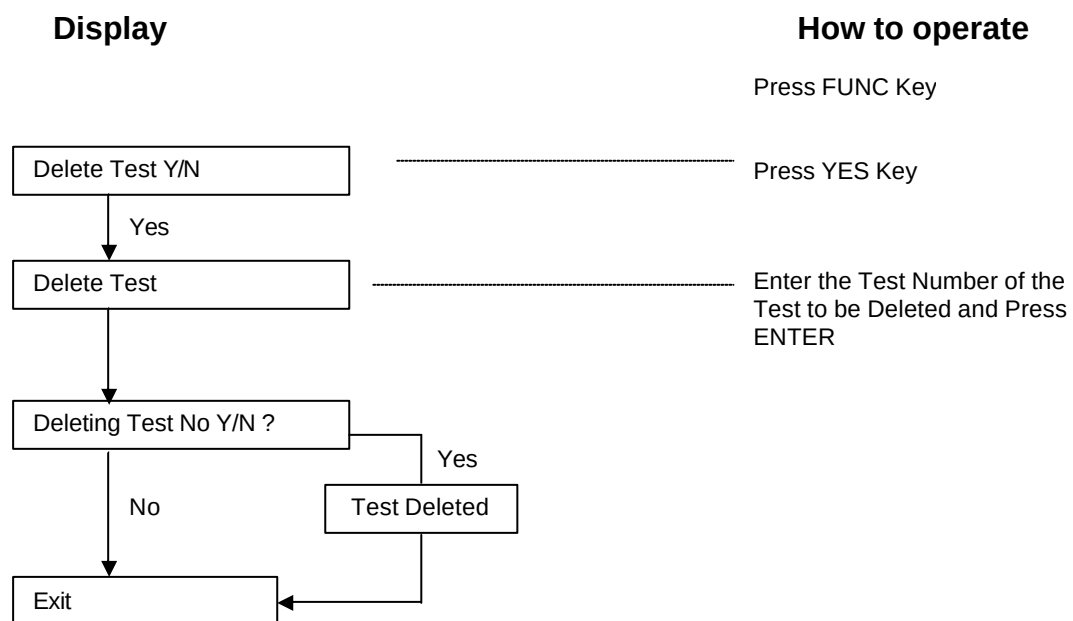


8.1.1 Saving Test:

To save the programmed test under any programming Mode



8.1.2 Deleting test:



8.1.3. Setting Date and Time:

(Please refer point No. 6.9)

8.2. Menu Key:

This key is used to recall the test number to be performed.

Display

Choose Test

How to operate

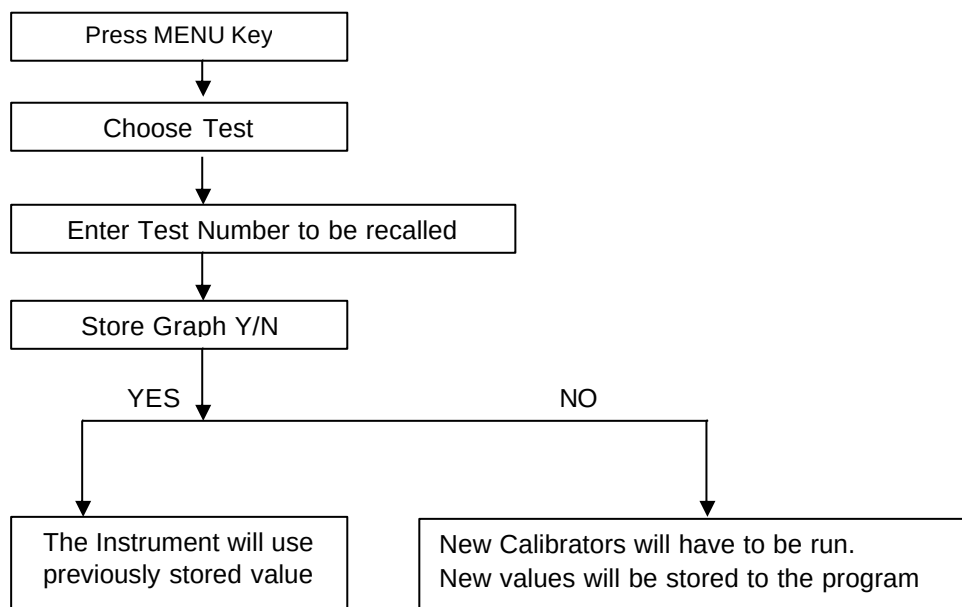
Press the MENU key
CHOOSE TEST

Enter the test number and
press ENTER key

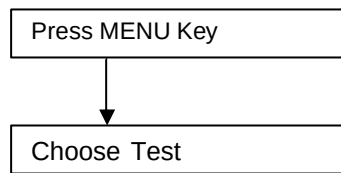
8.2.1. Enter Clinic Name:

(Please refer point No 6.10)

8.2.2. Recalling Saved Test:



8.2.3. Listing Saved Test:



Press 129 & Press Enter
The Instrument will print a list of saved Tests

8.3. LAMP Key:

This Key is used to switch the Lamp ON/OFF.

8.4. PAUSE Key:

This key is used to enable or disable the PAUSE function. When Pause is enabled, the STRIP will move only when you press ENTER after each well reading.

When Pause is disabled, the STRIP moves automatically and wells are read in sequence. This function is available in all modes.

8.5. CLEAR Key:

Press once to go to the previous position and press twice exit.

8.6. ENTER Key:

To either entering to data or proceed any test.

8.7. INTRP Key:

The sample may be labeled as positive or negative according to the user entered criteria, by pressing INTRP key this function can be accessed. The positive and negative cut-off limits can be selected for all the modes except ABSORBANCE and CUT-OFF modes and should be selected just before loading the STRIP. Either of the cut-off limit values can be bypassed by pressing ENTER key when prompted.

The criteria used could be either a single upper cut-off or both upper and lower cut-offs. When a single upper cut-off is used, any concentration, which is equal to or greater than the cut-off, will be labeled as positive. All other samples will be labeled as negative. If both upper and lower cut-off are used then the concentrations, which are greater than or equal to the upper cut-off, are labelled as positive, but only concentration less than the lower cut-off will be labelled as negative. The remaining valued label as equivocal.

OPERATION

Press INTRP key

Display

POSITIVE > =

NEGATIVE < =

How to operate

Enter a concentration value above which all the samples would be considered as positive for that test

Press Enter Key

Enter a concentration value above which all the samples would be considered as positive for that test

Press Enter Key

Press Enter Key each time if no concentration is given

8.8. CTRL Key:

- o It is possible to include the Quality control for Assay
- o The upper and lower limits (range) of the controls
- o After the Instrument is ready for reading the strip containing the control
- o With the help of CTRL key values for control can be fed. The control option can be used for all modes except the Absorbance mode and Cut-off mode.

OPERATION

Press CTRL key

Display

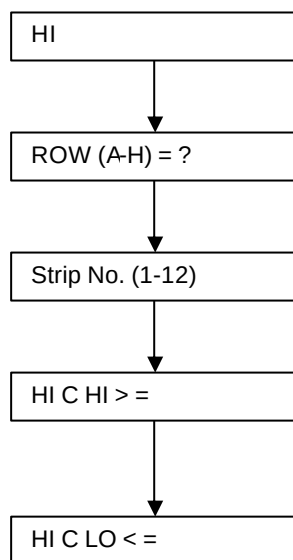
CONTROLS "HI =1" "LO = 0"

How to operate

Select either one of the options by pressing corresponding number key and enter the high or low control values.

On Pressing Key 1 – for High Control

Display



How to operate

Press Enter Key

Enter Row number in(if you are running in consecutive strips) which high control has been dispensed
(Key No. 1 =A, 2=B,3=C, 4=D, 5=E

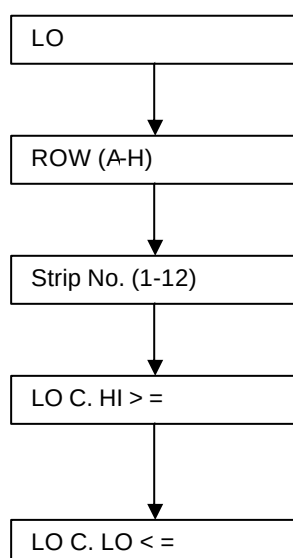
Enter well number in which high control has been dispensed in the range of high control. Enter the lower value of the range

The range of high control, here enter the higher value of the range.

Press Enter Key

On Pressing Key 0 – for LO Control

Display



How to operate

Press Enter Key

Enter Row number in (if you are running the control in the consecutive strips) which Low control has been dispensed
(Key No. 1 =A, 2=B,3=C, 4=D, 5=E

Enter well number in which high control has been dispensed. Enter the higher limit of the high control

Enter the lower limit of the low control

Press Enter Key

9. GENERAL FUNCTIONS

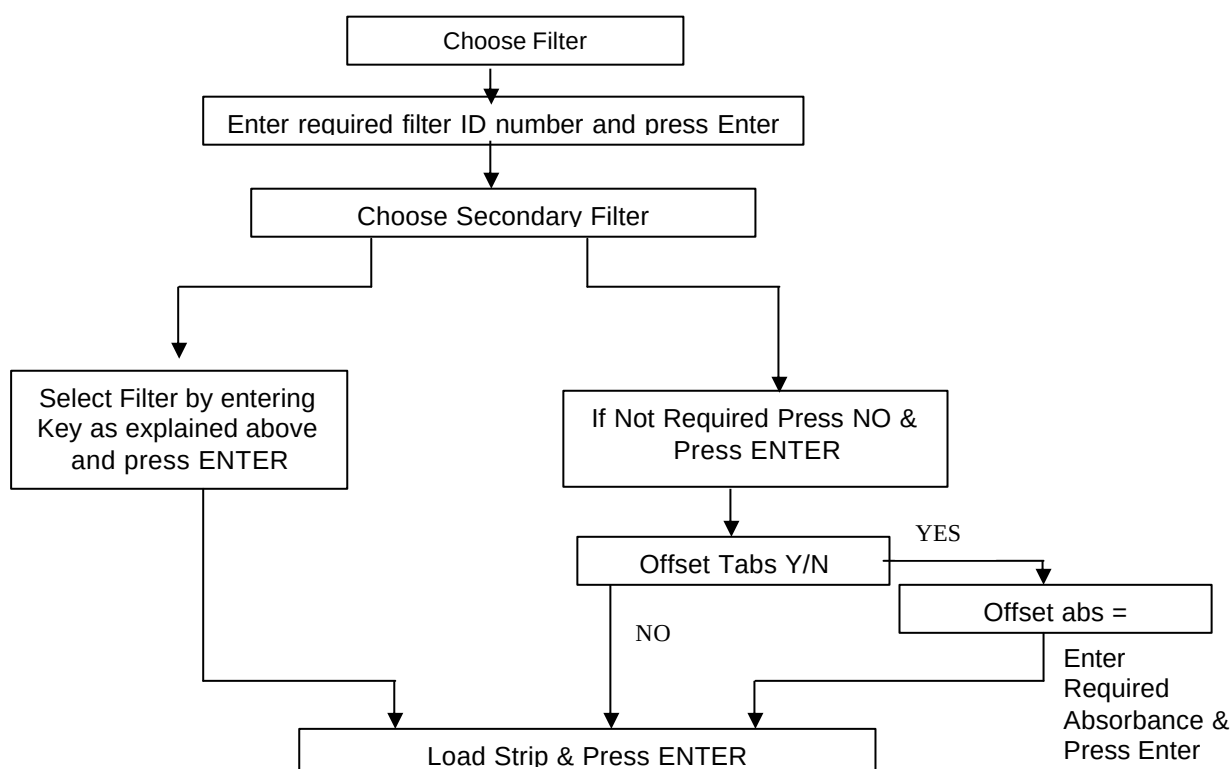
9.1. Selecting Primary and Secondary Filters:

The instrument asks the operator to select the primary and secondary filters. Select the filter using identification number given below. In all modes the operation begins by asking the filter to be selected. The followings 4 filters have been provided.

Filter Identification Key No.	Filter Wavelength
1	405 nm
2	450 nm
3	492 nm
4	630 nm

Operation

After selecting programming mode instruments prompts for filter selection



Blank can also be selected by pressing blank key just before the instrument starts reading the first strip. The Instrument will read every well at both wavelengths, and calculate the absorbance.

9.2. Blanking:

The blank material must always be in the 1st well and is always read singly, except in cut-off mode. The absorbance of this well is automatically subtracted from subsequent absorbance measurements before printing and calculating.

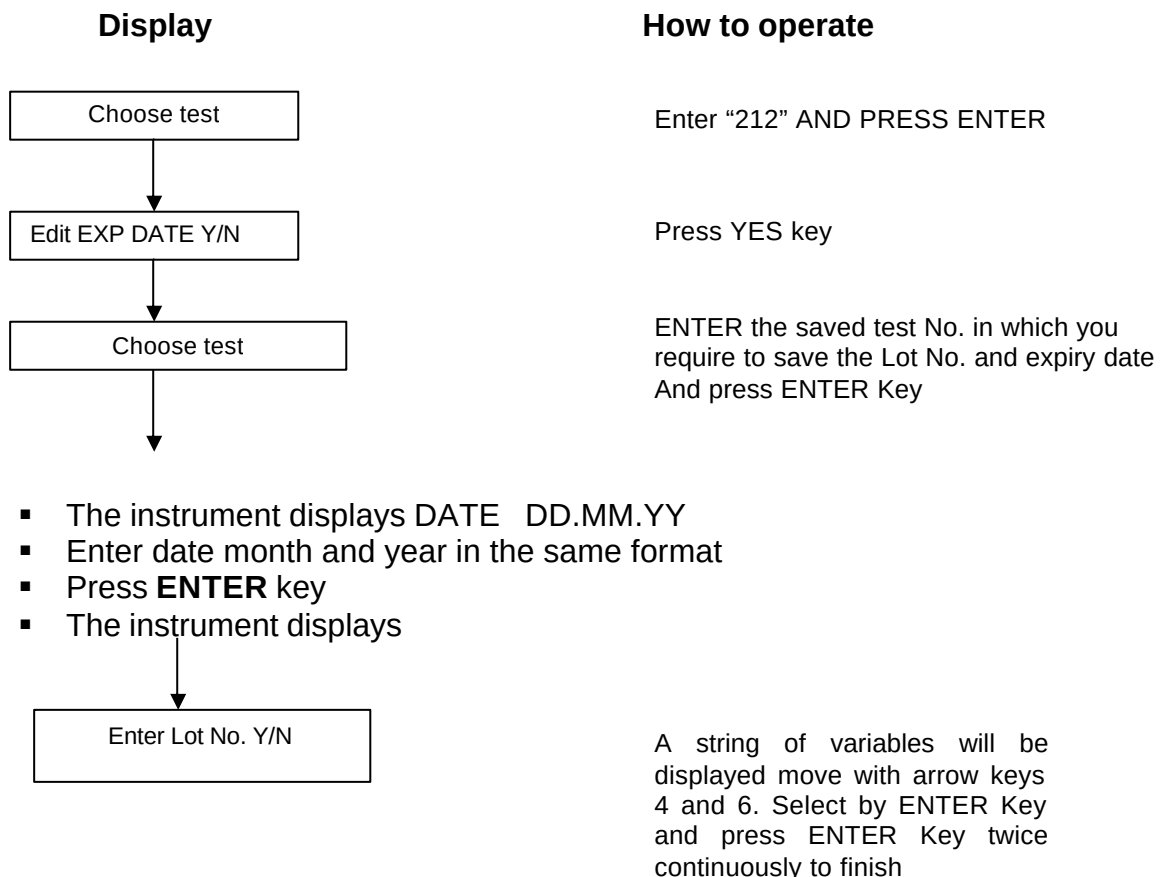
In the SINGLE CALIBRATOR MODE and the % ABSORBANCE MODE, the first well is automatically treated as a Blank. Blanking is not mandatory for the other calculation modes. However, if selected, the first well is always treated as a blank by the instrument.

Blanking can be selected by pressing the BLANK key before loading the STRIP.

9.3. To enter Lot No. and Expiry Date:

To enter expiry date and lot No., test has to be saved first.

Press MENU key



Now when Recalled, Expiry date and Lot No. Will be printed as well as displayed.

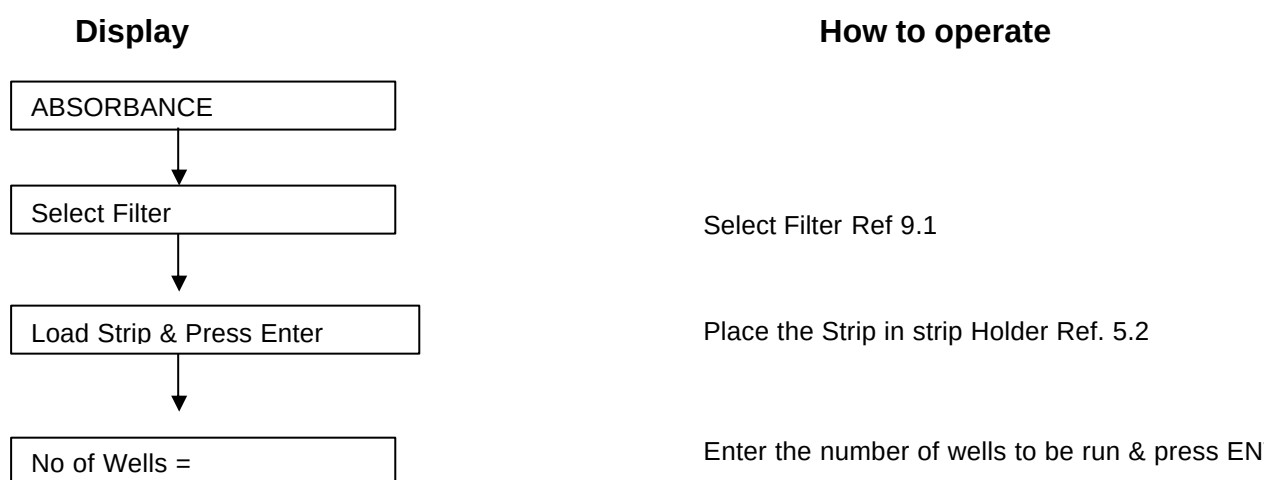
10. PROGRAMMING MODE

10.1. Absorbance:

In this mode the instrument reads and prints the monochromatic and bichromatic differential absorbance at the user selected wavelengths. Blanking is optional.

OPERATION

Use ABS key to enter the mode



The instrument loads the STRIP on the optical system, reads all the wells in sequence and transports them out again.

After the STRIP has been read, load the second STRIP and press ENTER. Continue the operation till all the Strips are read.

10.2. Single Standard Mode:



In this mode the instrument accepts the calibrator singly or in duplicate and then calculates the concentration based on the single point standard curve passing through the point 0.0. A blank is mandatory in the first well. A factor is generated in this mode and then multiplied by subsequent absorbance to determine the concentration.

A single calibrator/standard of a known concentration is used to calibrate the instrument so that the concentration of unknown samples can be calculated according to Beer's Law. The absorbance is read at user-selected wavelengths. The instrument will automatically blank on the first well and subtract its absorbance from each subsequent well. The second well is treated as the calibrator/standard well. The third well is also treated as calibrator/standard well if the calibrator/standard is in duplicate.

CALCULATION (Calculated by the instrument)

Factor = Concentration of the calibrator / Absorbance of the calibrator.

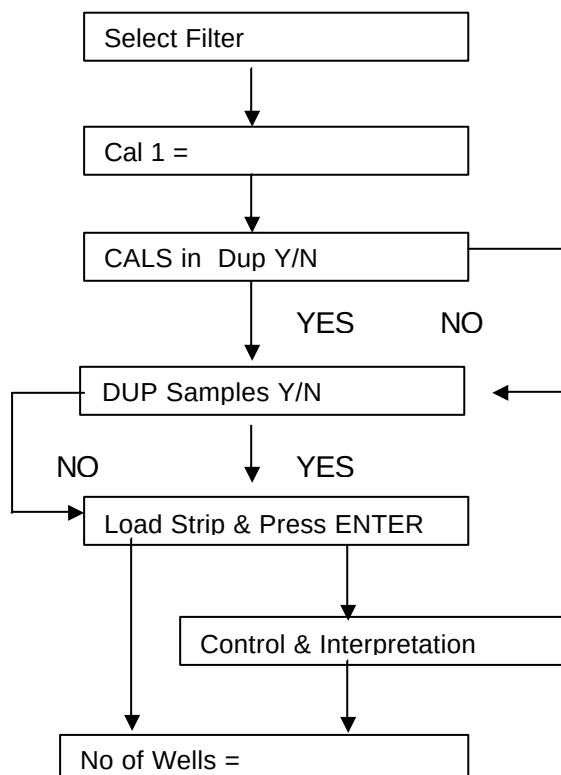
Sample Concentration = Factor x Sample absorbance.

The first well should always contain the BLANK.

OPERATION

Press STND key

Display



How to operate

Select Filter (Ref 9.1)

Enter Concentration value of the Calibrator

Press YES to select or NO to reject it

Place the Strip in strip Holder Ref. 5.2

Ref 8.8 & 8.7

Enter the number of wells to be run & press ENTER

The instrument again displays LOAD STRIP AND PRESS ENTER, place the STRIP on the STRIP track carefully, press ENTER key. The instrument loads the STRIP on to the optical system reads all the wells in sequence and transports them. The readings are displayed as well number BLANK/ CALIBRATOR/ SAMPLE identification and absorbance. Mean absorbance is printed, in case the calibrator and sample are run in duplicates.

10.3. A) Cut-Off Mode:

In this mode a cut-off point is determined for interpretation of specimens as per formula given in the reagent manual the negative controls are read followed by the positive controls, Cut-off control, low positive control. Blanking on the first well is optional. The instrument calculates the mean of the negative controls and the mean of the positive control, Cut-off controls, Low positive is also calculated.

OPERATION CALCULATION

$$C/O = X * MNC + Y * MPC + W * MCC + Z * MLPC + \text{Cut-off Factor.}$$

C/O : Cut-off absorbance.

MNC : Mean of the negative controls.

MPC : Mean of the positive controls.

MCC : Mean of cut-off control.

MLPC : Mean of low positive controls.

X, Y, W, Z are user entered coefficients as given in the interpretation criteria of the test that can have any positive or negative numerical value including 0 and 1.

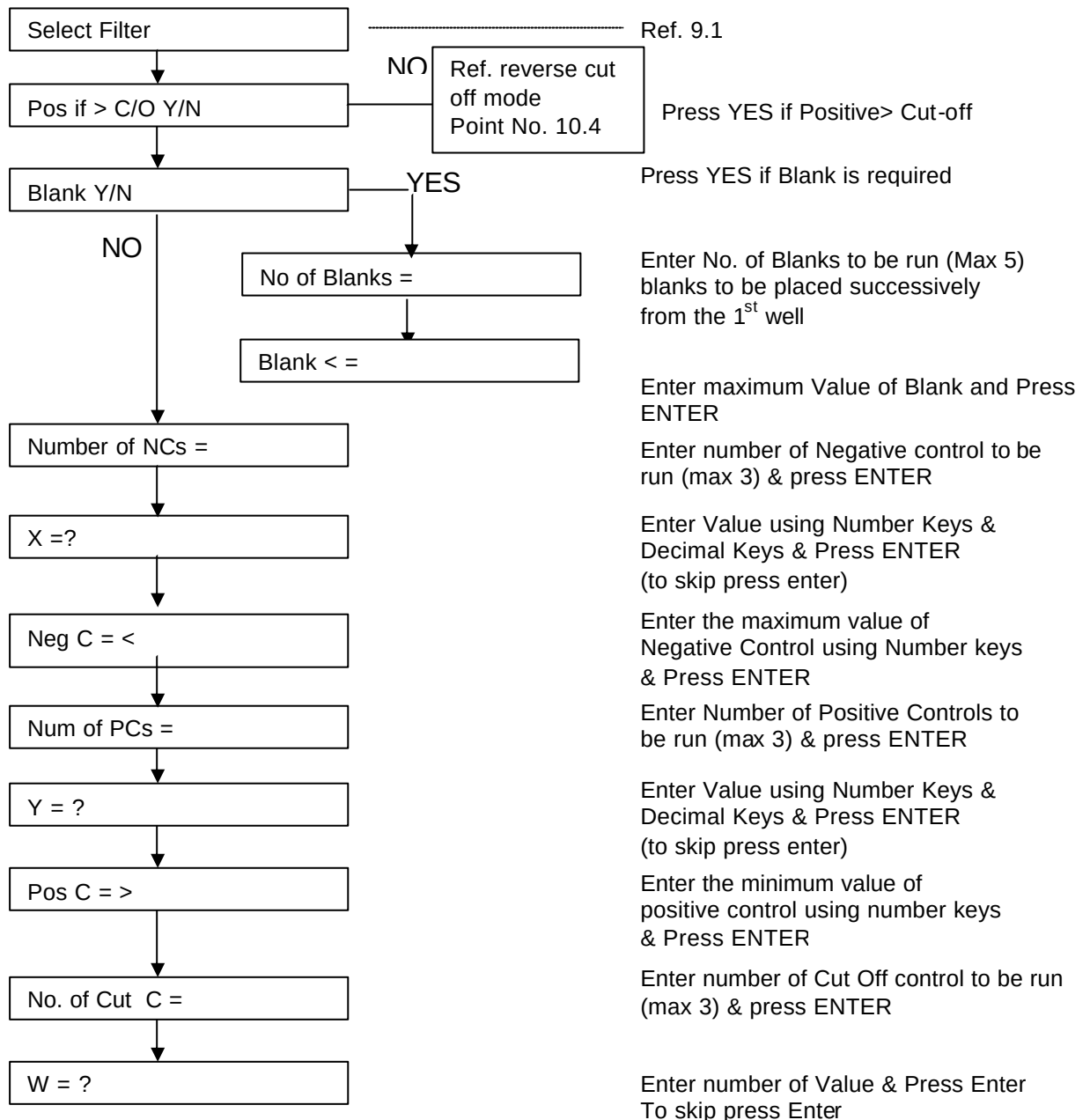
(X and Y can be entered up to two decimal places, while Cut-off Factor can be entered up to three decimal places).

OPERATION

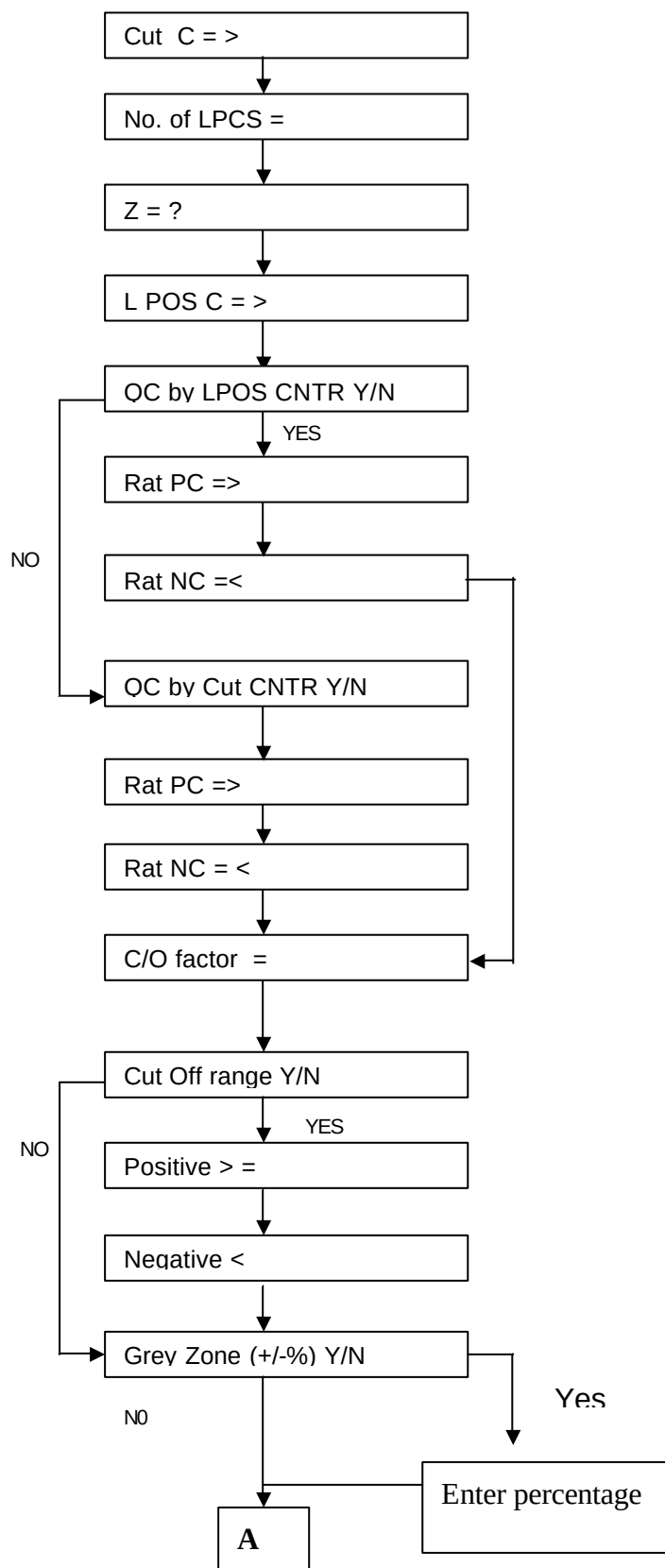
Press CUT key

Display

How to operate



Display



How to operate

Enter Value using Number Keys & Decimal Keys & Press ENTER

Enter number of Low Positive control to be run (max 3) & press ENTER

Enter Value using Number Keys & Decimal Keys & Press ENTER
(to skip press enter)

Enter minimum Value using Number Keys & Decimal Keys & Press ENTER

Quality Control by Low Positive Control

This is the minimum ratio of PC/LPC.
Enter Value using Number Keys & Decimal Keys & Press ENTER

This is the maximum ratio of NC/LPC.
Enter Value using Number Keys & Decimal Keys & Press ENTER

Quality Control by Cut off Control

This is the minimum ratio of PC/CC.
Enter Value using Number Keys & Decimal Keys & Press ENTER

This is the maximum ratio of NC/CC.
Enter Value using Number Keys & Decimal Keys & Press ENTER

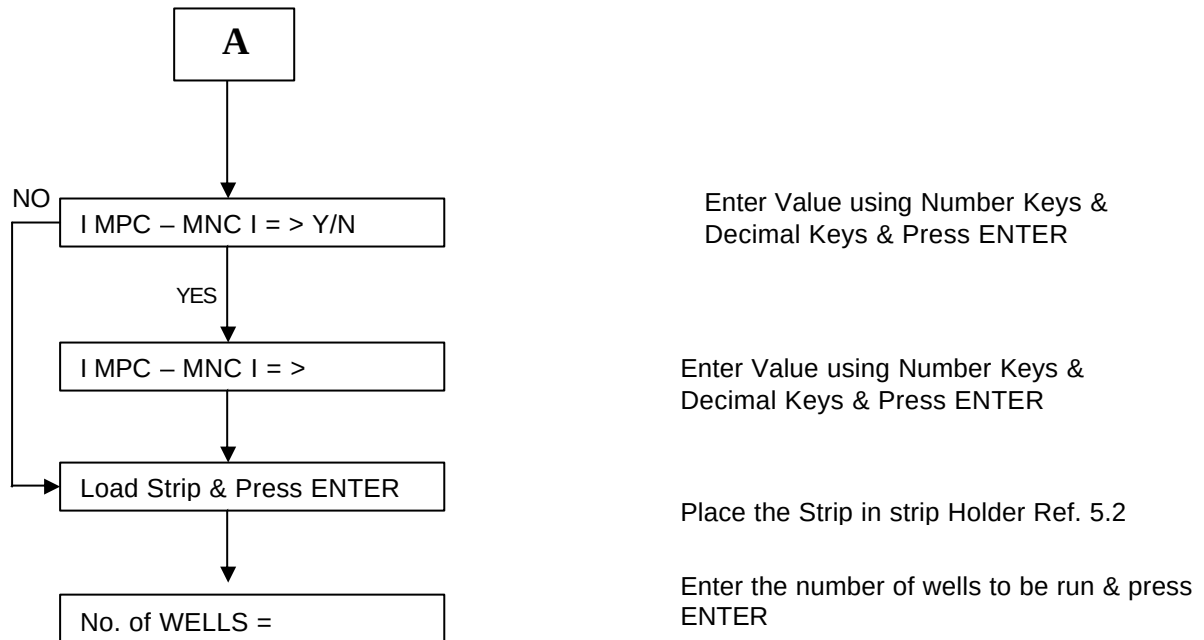
Enter Factor as given in the kit

Enter Cut off range as given in the kit

Enter Value using Number Keys & Decimal Keys & Press ENTER

Enter Value using Number Keys & Decimal Keys & Press ENTER

Enter Grey Zone Value in terms of %



The instrument loads the STRIP on to the optical system, reads all the wells in sequence and transports them out again. Press ENTER key, to continue the operation, till all the Strips are read.

10.3. B) Reverse Cut-Off Mode:

CALCULATION:

$$C/O = X * MNC + Y * MPC + W * MCC + Z * MLPC + \text{Cut off Factor.}$$

C/O Cut-off absorbance.

MNC Mean of the negative controls.

MPC Mean of the positive controls.

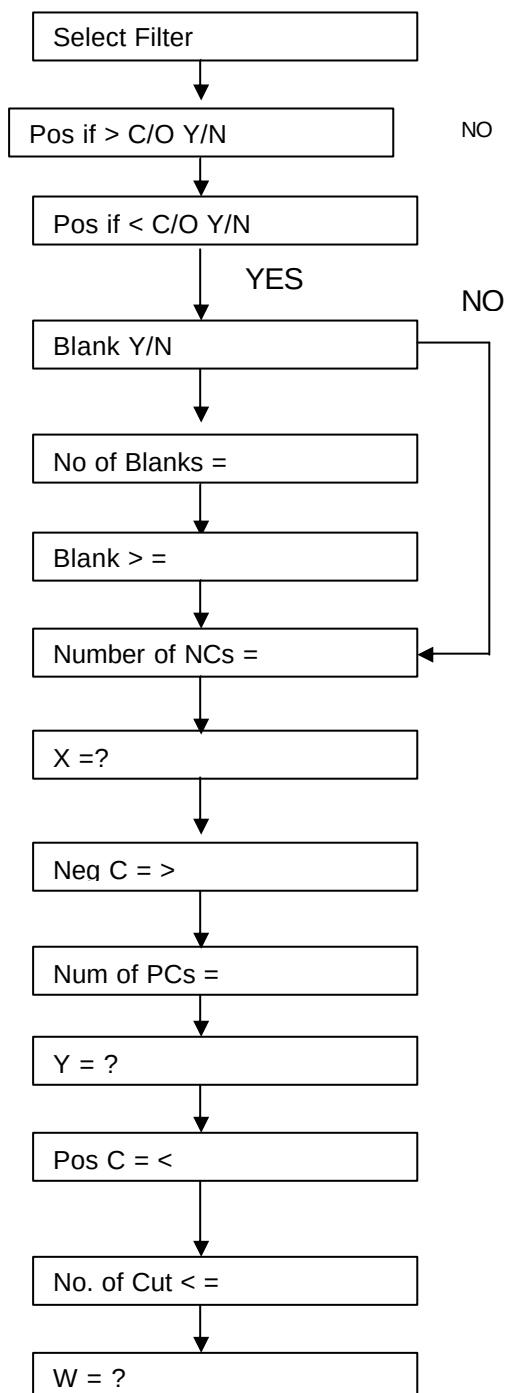
MCC Mean of Cut-off control.

MLPC Mean of low positive controls.

X, Y, W, Z User entered coefficients as given in the interpretation criteria of the test that can have any positive or negative numerical value including 0 and 1. (X and Y can be entered to two decimal places, while FAC can be entered to three decimal places).

OPERATION
Press CUT key

Display



How to operate

Ref. 9.1

Press NO if Positive < Cut-off (i.e Reverse Cutoff)

Press YES if Positive < Cut-off

Press YES if Blank is required

Enter No. of Banks to be run (Max 5) blanks to be placed successively from the 1st well

Enter Value of Blank and Press

Enter number of Negative control to be run (max 3) & press ENTER

Enter Value using Number Keys & Decimal Keys & Press ENTER (to skip press enter)

Enter number Negative Control using Number keys & Press ENTER

Enter Number of Positive Controls to be run (max 3) & press ENTER

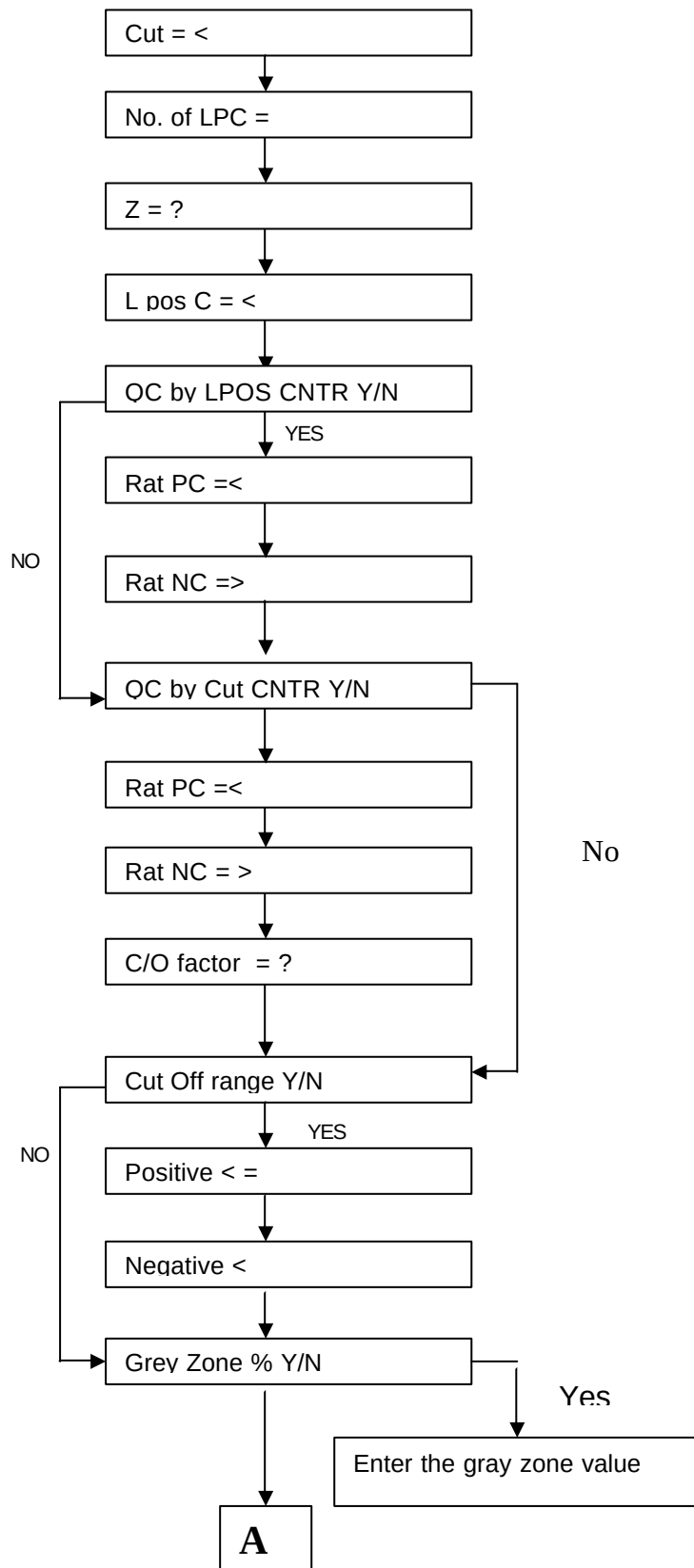
Enter Value using Number Keys & Decimal Keys & Press ENTER (to skip press enter)

Enter Number positive control using number keys & Press ENTER

Enter number of Cut Off control to be run (max 3) & press ENTER

Enter number of Value & Press Enter (to skip press enter)

Display



How to operate

Enter Value using Number Keys & Decimal Keys & Press ENTER

Enter number of Low Positive control to be run (max 3) & press ENTER

Enter Value using Number Keys & Decimal Keys & Press ENTER
(to skip press enter)

Enter Value using Number Keys & Decimal Keys & Press ENTER

Quality Control by Low Positive Control

This is the maximum ratio of PC/LPC.
Enter Value using Number Keys & Decimal Keys & Press ENTER

This is the minimum ratio of NC/LPC.
Enter Value using Number Keys & Decimal Keys & Press ENTER

Quality Control by Cut off Control

This is the ratio of PC/CC. Enter Value using Number Keys & Decimal Keys & Press ENTER

This is the ratio of NC/CC. Enter Value using Number Keys & Decimal Keys & Press ENTER

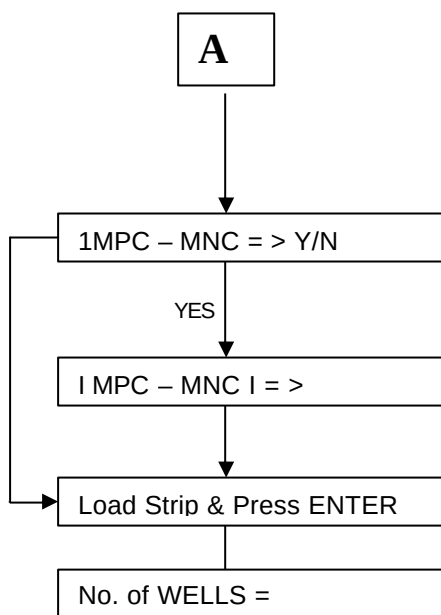
Enter Factor as given in the kit

Enter Cut off range as given in the kit

Enter Value using Number Keys & Decimal Keys & Press ENTER

Enter Value using Number Keys & Decimal Keys & Press ENTER

Enter Grey Zone Value in terms of %



Enter Value using Number Keys &
Decimal Keys & Press ENTER

Enter Value using Number Keys &
Decimal Keys & Press ENTER

Place the Strip in strip Holder Ref. 5.2

Enter the number of wells to be run & press
ENTER

The instrument loads the STRIP on to the optical system, reads all the wells in sequence and transports them out again. Press ENTER key, to continue the operation, till all the Strips are read.

10.4. Multi Standard Mode:

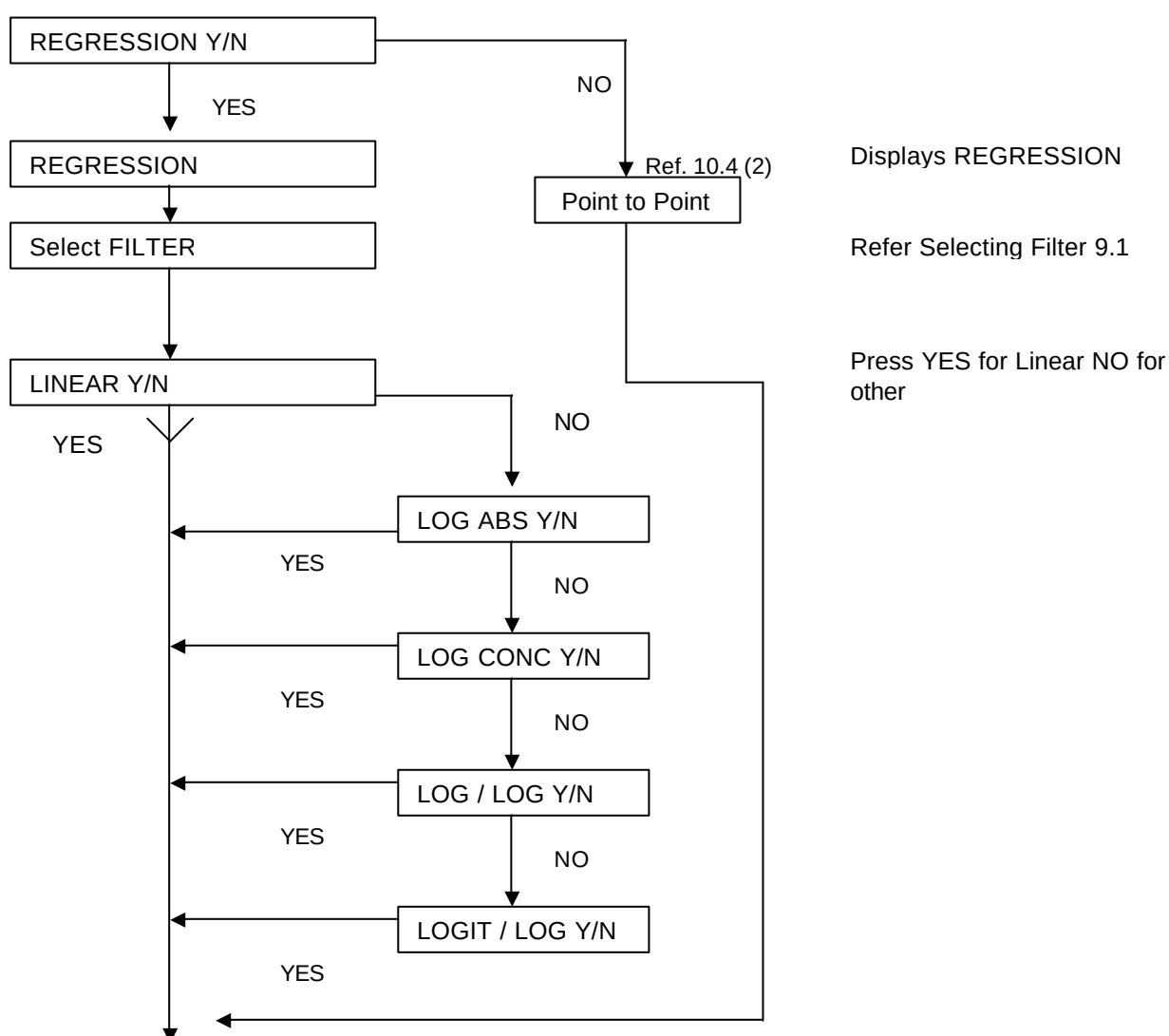
In this mode the instrument accepts a maximum of 7 calibrators and calculates concentration based on the best-fit curve. Graph is printed with Absorbance on Y-axis and concentration on X-axis.

OPERATION

Press REGRE key

Display

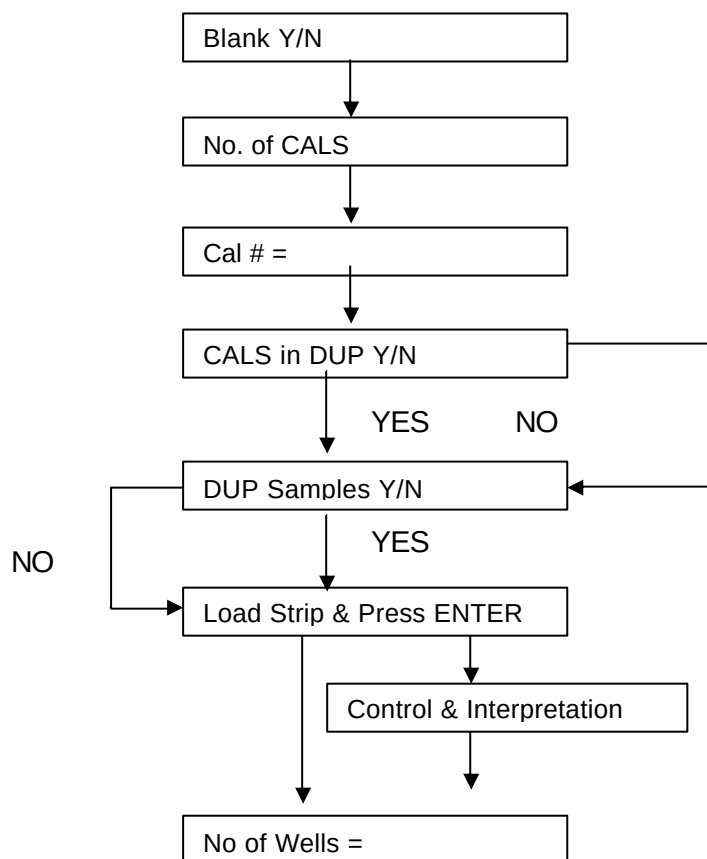
How to operate



10.4.1. Linear Mode:

OPERATION

Display



How to operate

Press YES key for Blank Selection

Enter Total number by using number keys (min 2 max 7)

Enter Concentration of Calibrators by using number keys.

Press YES for duplication of Calibrators

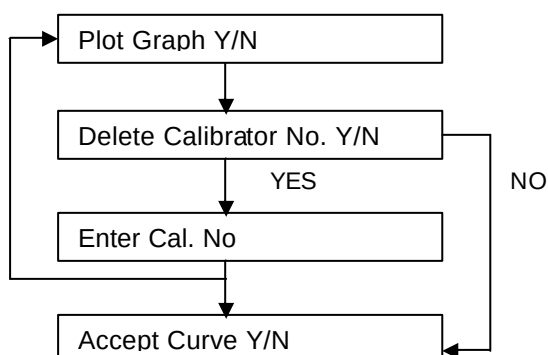
Press YES for duplication of Samples

Place the Strip in Strip Holder Ref. 5.4

Ref. 8.8 and 8.7

Enter the number of wells to be run & press ENTER

Instrument Display

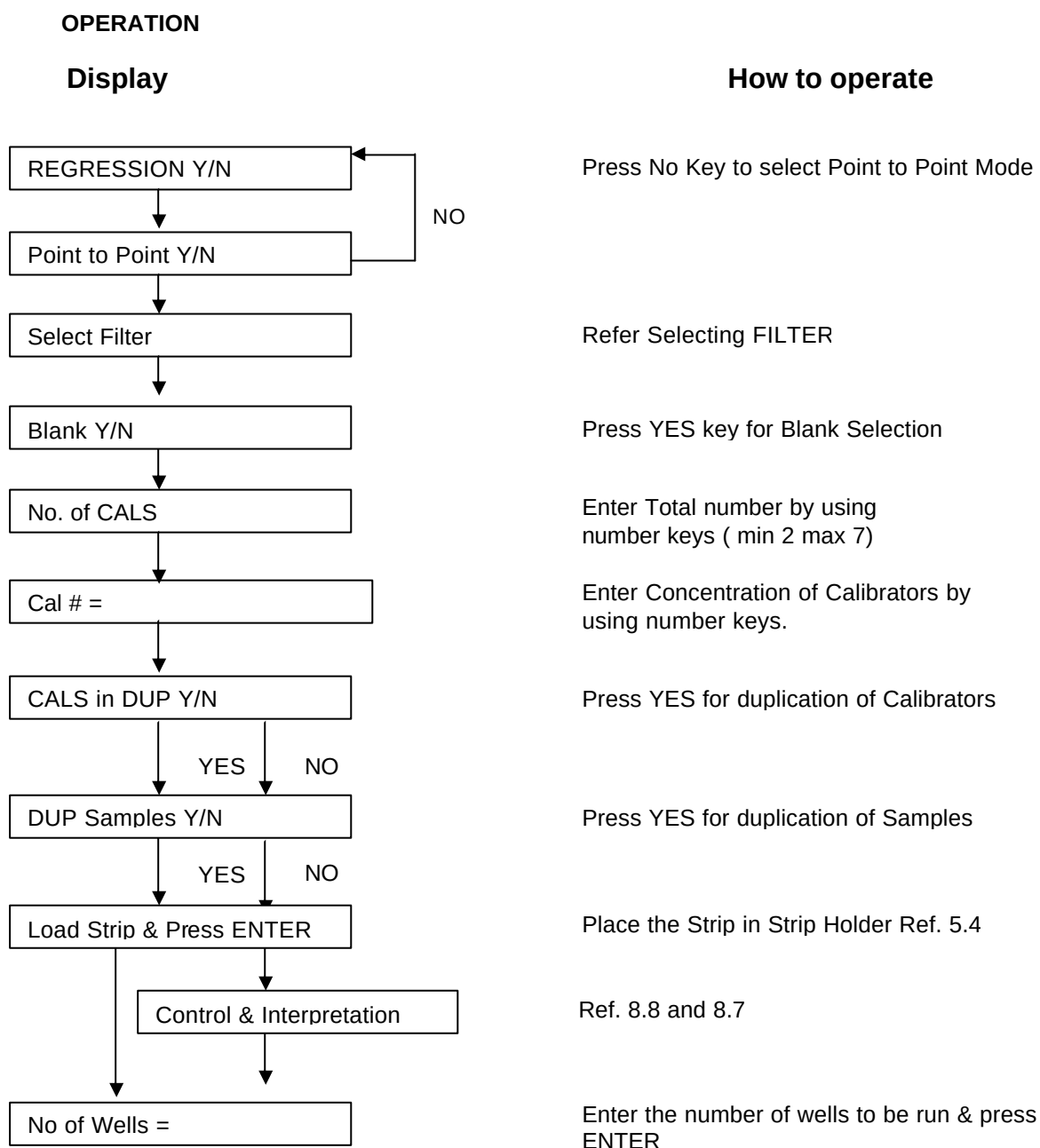


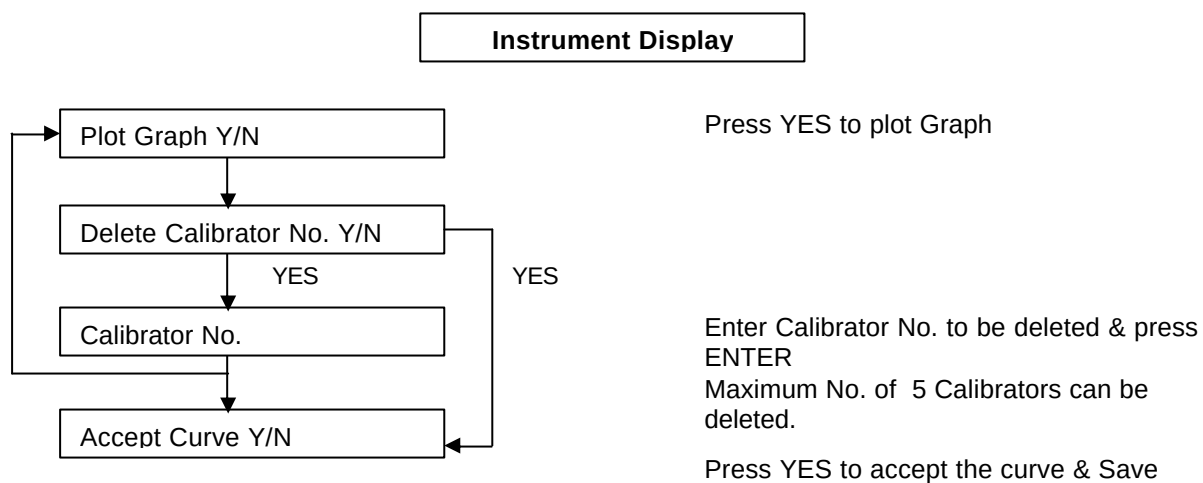
Press YES to plot Graph

Enter Calibrator No. to be deleted & press ENTER
Maximum No. of 5 Calibrators can be deleted

Press YES to accept the curve & Save

10.4.2. Point to Point Mode:





10.4.3. Plotting Graph:

After all wells have been read the instrument plots the graph

OPERATION

Display

How to operate

PLOT GRAPH Y/N

Press YES Key to Plot Graph on the Printer

The user can continue reading the next STRIP, by loading the STRIP and pressing ENTER key.

10.5. Percentage Absorbance Mode:

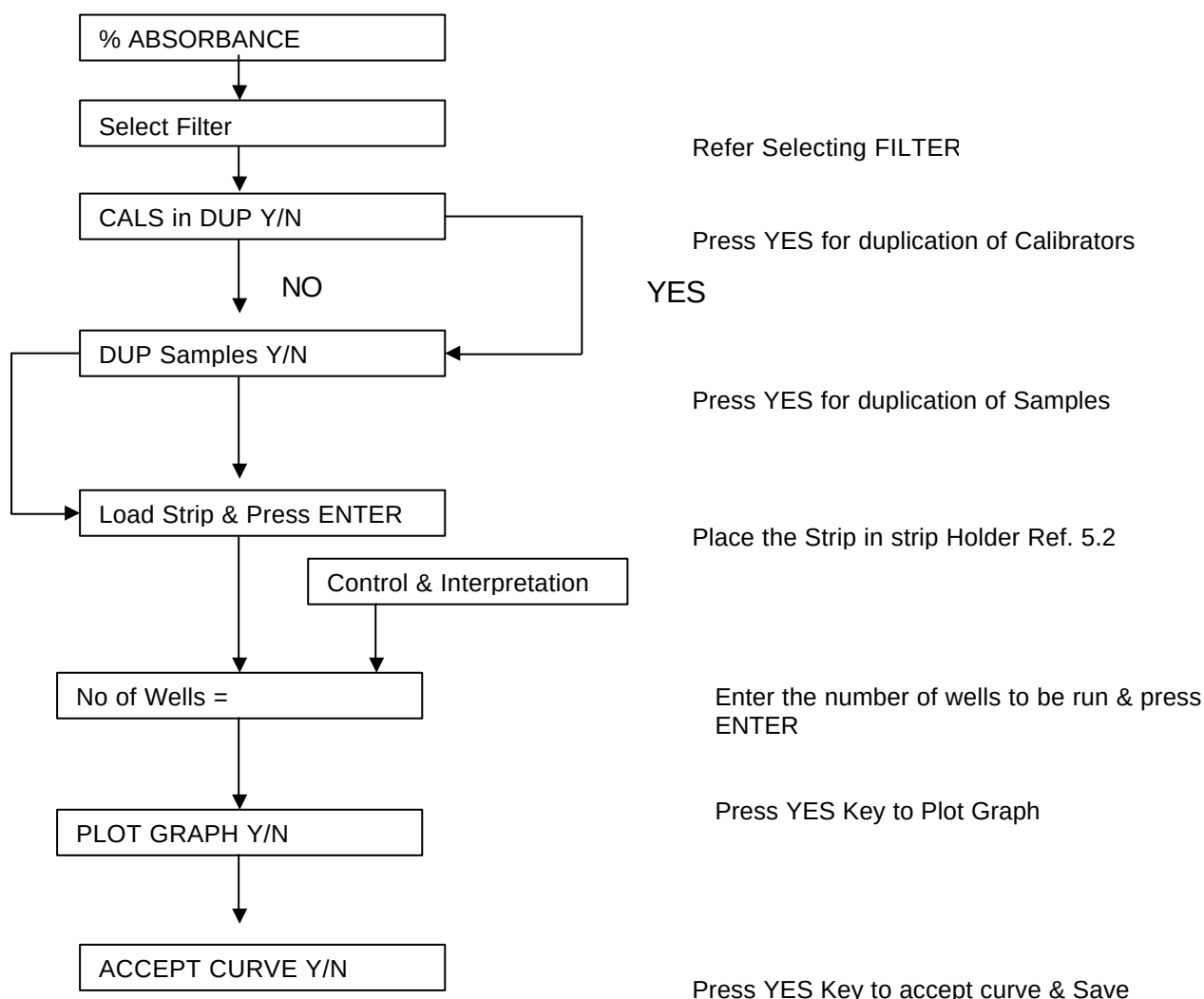
The Percent Absorbance Mode requires one calibrator (read singly or duplicate). In this mode a single calibrator, is considered to have an absorbance of 100%. The absorbance's of unknown samples are read and compared to the calibrator absorbance, and reported as % absorbance of calibrator. DATA INTERPRETATION and CONTROL OPTION can be used in this mode. Blank is compulsory on the first well.

OPERATION

Press % ABS Key

Display

How to operate



The instrument now reads the samples and displays/prints results as per the graph.

11. MAINTENANCE

- ◆ No regular maintenance required for this instrument.
- ◆ To ensure maximum trouble free operation, the instrument should be kept dry and clean. The ambient temperature should be maintained within 18°C to 37°C.
- ◆ Extreme humidity or temperature is harmful to filters.
- ◆ Temperature change at the rate of more than 5°C per minute is harmful.
- ◆ Cleaning may be done using a dry cloth.
- ◆ Do not open the instrument without proper training from technical personnel.
- ◆ Keep the instrument covered, when not in use.

12. TROUBLE SHOOTING

ERROR MESSAGE	CORRECTIVE ACTION
Memory Full	If Number of saved tests exceeds 125 tests then delete the unwanted tests.
Lamp Amplitude is poor	Inform the Service Engineer.
Readings are not Consistent	Place the STRIP properly and re-run the samples.
Controls Full	Number of controls exceed the set value.
Invalid Assay	If the Assay value is not valid this error appears. Re-Check the value and rerun the test.
To set printer	Switch on the Printer. Keep the printer online by pressing the online key.
STRIP Movement Jam	Reset the instrument by pressing the CLEAR key twice or Switch OFF and Switch ON the instrument. Insert the STRIP properly and return.
Sensor Movement Jam	Reset the instrument by pressing the CLEAR key twice or Switch OFF and Switch ON the instrument. Insert the STRIP properly and return.
ERROR MESSAGES IN CUT-OFF MODE	
Blank High	Blank value greater than the specified range.
Negative Control High	Negative control greater than the specified range.
Positive Control Low	Positive Control Less than Specified range
Low Positive Control High	Low Positive Control Less than Specified range
RAT PC low	Ratio of PC/LPC or PC/CC is lower than Entered Value
RAT NC High	Ratio of PC/LPC or PC/CC is Greater than Entered Value
ERROR MESSAGES IN REVERSE CUT-OFF MODE	
Blank Low	Blank value less than the specified range.
Negative Control Low	Negative control less than the specified range.
Positive Control High	Positive Control greater than Specified range
Cut Off Control High	Cut Off Control greater than Specified range
Low Positive Control High	Low Positive Control greater than Specified range
RAT PC High	Ratio of PC/LPC or PC/CC is greater than Entered Value
RAT NC Low	Ratio of PC/LPC or PC/CC is lower than Entered Value

13. DECONTAMINATION

13.1. Decontamination Procedure:

If the instrument is to be shipped after being exposed to potentially hazardous material, it should be decontaminated. The following procedure outlines the method of decontaminating the instrument before packaging and shipment.

13.2. Purpose of Decontamination:

Decontamination minimizes the risk to all who come in contact with the instrument during shipping, handling, and servicing.

13.3. General Considerations:

- Any laboratory instrument that has been used for clinical analysis is considered a biohazard and should be decontaminated prior to handling. Intact skin is generally considered an effective barrier against infectious Organisms; however, small abrasions and cuts may not be always visible. Prophylactic gloves must be worn when handling instruments that have not been decontaminated. Gloved hands should be considered contaminated at all times and must be kept away from eyes, mouth and nose at all times.
- Mucous membranes are considered prime entry routes for infectious agents. Wear eye protection and a surgical mask when there is a possibility of aerosols.
- Eating and drinking while decontaminating instruments is not advisable.

13.4. Procedure:

- A solution of 0.5% Sodium Hypo Chlorite (NaOCL) solution (Bleach) is used. Commercial bleach is 5% NaOCL; household bleach is 3% NaOCL. When using commercial bleach, use a 10:1 mixture; if using household bleach, a 6:1 mixture is required. This is a caustic solution. It is important to wear gloves and eye protection when handling it.
- Wipe down the carrier and all exposed surfaces of the unit with the bleach solution. Remove the top shroud of the instrument and wipe down the top surface of the instrument base, as well as the inside of the top shroud.
- Reassemble the unit and discard the used gloves and towels.

14. SAFETY CLEARANCE CERTIFICATE

Please complete all information requests on this form prior to returning the instrument to the manufacturer or your local distributor for servicing, repairs or return. Thank you for your co-operation.

Customer _____ Contact _____

Address _____ Position _____

_____ Dept _____

_____ Tel: _____

Country _____ Fax: _____

Post Code _____

Model No. _____ Serial No. _____

Accessories

Returned _____

Date of Purchase (if known) _____

Complaint _____

Has the equipment been exposed to any of the following: (*delete as applicable)

a) Blood, body fluids, pathological specimens *YES/NO

If YES, please specify _____

b) Other Biohazard *YES/NO

if YES, Please specify _____

15. SPARE PARTS

15.1. Ordering Spare Parts:

Parts subject to deterioration, or defectives which need to be replaced, have to be ordered by giving following details.

Ordering the spare parts, the following data are to be mentioned:

- o Customer's purchase order No.
- o Name and version of the instrument.
- o Instrument code number.
- o Part code number.
- o Description of the part.
- o Requested quantity.
- o Name and company address for delivering the ordered goods.

While replacing the parts, the use of ORIGINAL SPARE PARTS guarantees the efficiency and a lasting instrument life.